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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/518,408 03/03/00 LUNDY

K PC10487A

023913
PFIZER INC
235 E 42ND STREET
NEW YORK NY 10017

HM22/0705

EXAMINER

JONES, D

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/518,408

Applicant(s)

LUNDY, KRISTIN M.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-21 are pending.
2. Claims 1-21 are rejected.

Priority

3. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Information Disclosure Statement

4. The information disclosure statement filed on May 12, 2000 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 13-21 recites the limitation "Formula I" in each of the claims. There is insufficient antecedent basis for this limitation in the claim. Each of these claims fails to provide a structure to coincide with compound of Formula I. It is recommended that the compound and the embodiments of Formula I be incorporated into independent claim 13 to obviate this anomaly.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villalobos et al. and Mimori et al. both in view of Ruehl et al.

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11. The prior art reference of Villalobos disclose of the administration of the heterocyclic-cyclic amine derivative compounds of Formula (I) for improving the memory of Alzheimer's patients. Villalobos et al. also disclose that these compounds are acetylcholinesterase inhibitors, (see section entitled Background of the Invention on page 1 and pages 1-6 under the section entitled Summary of the Invention).

12. Mimori et al. teach of treating the neurological disorder of Alzheimer's disease with inhibitors of acetylcholinesterase, (see abstract). Ruehl et al. teach that,

"a substantial number of elderly pet dogs are at risk for developing age-related medical and behavior disorders. Veterinary practitioners have long been aware of the occurrence of geriatric behavior problems in pet dogs, such as disturbance of normal sleep-wake cycles and housetraining. Such problems are usually referred to by pet owners and veterinarians as part of the 'old dog syndrome,' or, when severe, as 'senility,' and are incorrectly attributed by pet owners to 'simple aging' or 'normal aging.' [T]hese behavior problems can sometimes be associated with histologic lesions in the brains of affected dogs that are very similar to lesions observed at autopsy in humans with dementia of the Alzheimer's type, (see 1st paragraph, on page 283)."

13. Ruehl et al. further teach that the use of, "the term cognitive dysfunction [is] to refer to the age-related or geriatric onset behavior changes, (as cited from 3rd paragraph on page 283). Ruehl et al. also teach that the, "many behavior changes can be assigned to the following categories: 1) disorientation, 2) decreased or altered social interactions or responsiveness to family members, 3) loss of prior housetraining, 4) disturbances of the sleep/wake cycle, 5) and decreased activity, (see 2nd paragraph on page 284).

14. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

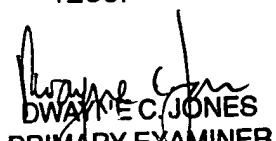
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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art reference of Ruehl et al. equate the Alzheimer's dementia in humans with cognitive dysfunction of animals. Accordingly, it would have been obvious to one having ordinary skill in the art to combine methods of treatment and the pharmaceutical compositions as taught by Villalobos et al. and Mimori et al. along with treating the cognitive dysfunctions in animals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
June 28, 2001